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510(k) Summary of Safety and Effectiveness for the Dimension® EXL™ LOCI® NTP Calibrator (RC623)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: K082680

B. Date of Preparation: August 26, 2008

C. Proprietary and Established Names:
Dimension® EXL™ LOCI N-terminal Pro-Brain Natriuretic Peptide Calibrator (LOCI NTP Calibrator - RC623)

D. Applicant:
Siemens Healthcare Diagnostics Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Senior Manager, Regulatory Affairs
Office: (302) 631-0376 Fax: (302) 631-6299

E. Regulatory Information:
1. Regulation section: 21 CFR § 862.1150 Calibrator, Secondary
2. Classification: Class II
3. Product Code: JIT, Calibrator, Secondary
4. Panel: Clinical Chemistry

F. Predicate Device:
The LOCI NTP Calibrator (RC623) is substantially equivalent to the Dimension Vista® PBNP Calibrator (KC676A) cleared under K080578.

G. Device Description:
The LOCI NTP CAL is a frozen liquid product containing synthetic human N-terminal pro-brain natriuretic peptide in bovine albumin matrix with stabilizers and preservative. The kit consists of ten vials, two vials per level (A, B, C, D, and E), 1.0 mL per vial. Description of the manufacturing, value assignment and stability testing process are provided in this submission report.

H. Intended Use:
The LOCI NTP CAL is an *in vitro* diagnostic product for the calibration of the N-terminal pro-brain natriuretic peptide (NTP Cat. No. RF623) method on the Dimension® EXL™ integrated chemistry system with LOCI® Module.

I. Substantial Equivalence Information:
The LOCI NTP Calibrator (RC623) and the predicate Dimension Vista® PBNP Calibrator (KC676A) were compared. A comparison of the important similarities and differences between the devices and the predicates is provided in the following table:

Feature	LOCI NTP CAL	Dimension Vista® PBNP Flex® Calibrator (KC676A) (K080578)
Intended Use	The LOCI NTP CAL is an *in vitro* diagnostic product for the calibration of the N-terminal pro-brain natriuretic peptide (NTP Cat. No. RF623) methods on the Dimension® EXL™ integrated chemistry system with LOCI® Module.	The PBNP CAL is an *in vitro* diagnostic product for the calibration of the N-Terminal Pro-Brain Natriuretic Peptide (PBNP) method for the Dimension Vista® System.
Analyte	Synthetic PBNP	Synthetic PBNP
Matrix	Bovine Albumin	Bovine Albumin
Form	Liquid, frozen	Liquid, frozen
Volume	Ten vials, two vials per level (A, B, C, D, and E), 1.0 mL per vial.	Ten vials, two vials per level (A, B, C, D, and E), 1.0 mL per vial.
Levels	Five Levels, (0, 250, 1500, 12,000, 36,750 pg/mL)	Five Levels, (0, 250, 1500, 12,000, 36,750 pg/mL)

J. Conclusion:

The Dimension® EXL™ LOCI N-terminal Pro-Brain Natriuretic Peptide Calibrator (RC623) is substantially equivalent to the predicate Dimension Vista® PBNP Calibrator (KC676A) cleared under K0080578. Comparative testing described in the protocol included in this submission demonstrates substantial equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 0 2008

Siemens Healthcare Diagnostics, Inc.
c/o Mr. Victor Carrio
Senior Manager of Regulatory Affairs
P.O. Box 6101, Mail Stop 514
Newark, DE 19714-6101

Re: k082680
Trade Name: LOCI N-Terminal Pro-Brain Natriuretic Peptide Calibrator (RC623)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIT
Dated: September 12, 2008
Received: September 15, 2008

Dear Mr. Carrio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K082680

Device Name:

LOCI N-Terminal Pro-Brain Natriuretic Peptide Calibrator (RC623)

Indication For Use:

The LOCI NTP CAL is an *in vitro* diagnostic product for the calibration of the N-terminal pro-brain natriuretic peptide (NTP Cat. No. RF623) method on the Dimension® EXL™ integrated chemistry system with LOCI® Module.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082680